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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,084	01/28/2002	Jonathan David Bortz	60017600.0002	3232

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EXAMINER	
PETERSEN, CLARK D	

ART UNIT	PAPER NUMBER
1657	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/059,084	BORTZ ET AL.	
	Examiner	Art Unit	
	Clark D. Petersen	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *16-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 May 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 15 August 2006 is acknowledged. The traversal is on the ground(s) that instant claims 16-18, constituting Group II, would inherently be examined in the search for the claims of Group I, instant claims 1-15. Examiner accepts applicant's argument and the restriction requirement between Groups I and II is withdrawn. Examiner has examined instant claims 1-18.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement between the instant Groups I/II and III and IV, the election of Group I, as well the rejoined claims 16-18 of Group II, has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 19-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Groups, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 15 August 2006.

The requirement for restriction between Groups I/II and Group III and Group IV is still deemed proper and is therefore made FINAL.

Claims 1-37 are pending.

Claims 19-37 are withdrawn from examination.

Claims 1-18 were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The terms "normal" and "normoglycemia" recited in the tables in claims 9-11 and in the text of claims 12-15 are relative terms which render the claims indefinite. The terms "normal" and "normoglycemia" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Additionally, because the terms "hypoglycemia" and "hyperglycemia" depend on a definition of "normal" or "normoglycemia", these terms, too, are indefinite. The instant specification provides that "The blood glucose patterns of the present invention comprise clinically significant terms which identify clinically actionable distributions of blood glucose measurements but which do not presently have generally accepted definitions within the art of glucose reading analysis" (see p. 4, lines 10-12). The instant specification also states "In defining settings 102, the user may also define the blood glucose range which represents the normal range of glycemia or normoglycemia. The default and preferred standardized normal range is 71-150 mg/dL for all time categories except Before Breakfast. The default Before Breakfast normal range is 71-125 mg/dL. The normal range may be modified by the medical professional for each patient, each time period and at each time category, but once set, is the same for all analysis done within each time category" (see p. 6, line 18 to page 7, line 1). These passages support the indefinite nature of the instant claims 9-15, as the instant specification admits that the distributions of glucose measurements do not presently have

generally accepted definitions, and furthermore, the definitions of blood glucose measurements can be of any nature the user wishes. Therefore the terms "normal", "normoglycemia/normoglycemic", "hyperglycemia/hyperglycemic", and hypoglycemia/hypoglycemic" are undefined and unaccepted in the art.

Claim Rejections - 35 USC § 101/112, first paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9-15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specifically asserted utility or a well established utility. It is accepted that compromised control of blood glucose levels leads to serious medical complications for a patient. However the instant application provides no evidence that the system described in the instant claims and instant specification is relevant to diagnosis or management of any human disease related to glycemic control. The instant specification states "The blood glucose patterns of the present invention comprise clinically significant terms which identify clinically actionable distributions of blood glucose measurements but which do not presently have generally accepted definitions within the art of glucose reading analysis" (see p. 4, lines 10-12). Therefore applicants admit that their parameters have no acceptance in general medical practice for characterizing diseases involving blood glucose control. The instant specification fails to demonstrate how the terms are clinically significant, and how the distributions of blood glucose measurements are clinically actionable. The applicants provide only a single prophetic example (see p. 12 line 13 to p. 15 line 20). This example does not provide any actual collected data

demonstrating how such a method of blood glucose measurement would generate patterns. Additionally, the hypothetical example does not provide how the data collection and analysis is relevant to diagnosing or managing any disease that a patient such as Jane Doe, the subject of the Example in the instant specification, actually has; it hypothesizes only that blood glucose measurements can be performed.

Diagnostic methods and standards for a diseases involving glycemic control are established by the medical community (see Peters et al (Amer J Med, 1998), entire document, for example), through extensive population studies of disease states and correlations with blood glucose levels (see Peters et al, p. 16S, "Rationale for Previous Diagnostic Criteria", for example). Applicants have not demonstrated how collecting exactly 14 blood glucose data points, as recited in claim 9, for example, and measuring a percentage above and below an arbitrary "normal" reading provides medically useful information that substitutes for methods exemplified by Davidsohn et al, Peters et al, and additionally by the National Institute of Diabetes and Digestive and Kidney Disease website for monitoring and managing blood glucose.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specifically asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 6, 7, 12, 13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Davidsohn et al. (Clinical Diagnosis by Laboratory Methods, 1974). Davidsohn et al. teach methods of diagnosing diabetes. Davidsohn et al teach that several methods of diagnosing diabetes by measuring blood glucose levels exist. In particular, one can diagnose diabetes by examining a plurality of data from several forms of blood glucose tests ("Two-hour postprandial blood glucose", p. 606, col 2, for example). Davidsohn et al. teach that one should do a fasting glucose test on a suspected diabetes patient, and calculate blood glucose levels. If blood glucose levels fall into a "suspicious" category – i.e. between 110 and 120 mg/dL, a second oral glucose tolerance test should be performed, and the blood glucose levels again calculated, which reads on severity criteria of the suspected hyperglycemic condition. Additionally, Davidsohn et al. teach that when a caregiver performs an oral glucose tolerance test, if the results are abnormal, another test should be given, reading on instant claim 6, which recites that blood glucose should be calculated for a time period other than the predetermined time period. It is an inherent part of the procedure taught by Davidsohn et al. that a caregiver calculates the number, i.e. percentage, of readings within or outside the normal range of glycemia, as well as the mean of each reading, reading on instant claim 12. Additionally, it is the

object of the tests taught by Davidsohn et al. to count the number of readings above or below a glycemia threshold, reading on instant claim 13. It is also inherent in the tests described by Davidson et al. to calculate the number of readings above the glycemia threshold, and to detail the mean and quantity of readings outside normal glycemia threshold. Additionally, regarding claims 4, 6, and 7, which recite the recording of data in the form of a glycemic control report, this is an inherent step in generating a medical history for a given patient. Therefore the teachings of Davidsohn et al. are deemed to anticipate the instant claims 1, 2, 4, 6, 7, 12, 13, and 15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidsohn et al.

The teachings of Davidsohn et al. are discussed above and applied as before. Additionally, Davidson et al. suggest that one may perform more than two blood glucose measurement protocols on certain patients. For example, one can diagnose "prediabetic" patients. First a caregiver provides an initial glucose tolerance study. A second glucose tolerance study is then performed after the administration of a cortisone shot. In patients that have a blood glucose concentration of 140 mg/dL or higher after 2 hours, follow-up studies are

necessary, reading on instant claim 3 which recites that a third set of calculations are performed based on a predetermined normal range of criteria (see p. 608, bottom of col 1 and top of col 2, for example). Additionally, as discussed above it is standard medical practice to record the results of diagnostic tests in a patient's medical history, reading on instant claim 5, 16, 17, and 18. As stated for instant claim 6, when a glucose tolerance test is part of the protocol, it would be obvious to repeat the test if abnormal results are obtained due to patient illness (see p. 607, col. 1, for example), reading on instant claim 8.

A person of ordinary skill in the art at the time the invention was made would have been motivated to perform a third set of calculations on a plurality of blood glucose readings, because Davidsohn et al. teach that this is proper procedure in making a diagnosis among certain classes of patients, and it would be obvious to perform some sets of tests outside the predetermined time category, because Davidsohn et al. teach that sometimes the patient's condition mandates repeating certain blood glucose tests.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a third set of calculations on a patient, and on occasion perform these tests outside the predetermined time category.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571)272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDP
11/10/2006

JON WEBER
SUPERVISORY PATENT EXAMINER